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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/090,038	02/27/2002	James R. Komorowski	NUTRL023A	6775

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EXAMINER	
CHOI, FRANK I	

ART UNIT	PAPER NUMBER
1616	

NOTIFICATION DATE	DELIVERY MODE
05/02/2008	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

jcartee@kmob.com
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Office Action Summary	Application No.	Applicant(s)	
	10/090,038	KOMOROWSKI ET AL.	
	Examiner	Art Unit	
	FRANK I. CHOI	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *1/22/2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *7 and 38-54* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *7 and 38-54* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *1/22/2008*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 38-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over McCarty (US Pat. 5,789,401) or McCarty (US Pat. 5,929,066), each in view of de la Harpe et al. (US Pat. 5,948,772), Brand-Miller, Rath (US Pat. 6,693,129), Sears (US Pat. 6, 140,304) and Chung.

McCarty (US Pat. 5,789,401) or McCarty (US Pat. 5,929,066) were discussed in the prior Office Actions and the same are incorporated herein.

de la Harpe et al., Brand-Miller were discussed in the prior Office Actions and the same are incorporated herein. Further de la Harpe et al. discloses that chromium controls serum lipids, decreases LDL and increases HDL levels (Column 2, lines 30-38).

Rath discloses a composition containing biotin and chromium glycinate which is effective in lowering LDL and triglycerides which can be administered orally or parenterally, and that those skilled in that art would understand that changes can be made and equivalents substituted and that effective amounts may vary depending on variations in patients, durations of treatment, etc. and that modifications may made to adapt a particular situation and composition of matter (Column 5, lines 45-56, Column 6, lines 36-68, Column 7, Column 9, lines 1-33).

Sears discloses that insulin resistance due to hyperinsulinemia is commonly associated with increased glycosation of hemoglobin due to increased serum glucose levels and that

hyperinsulinemia is also associated with increased triglycercides, decreased HDL cholesterol levels and elevated percent body fat (Column 12, lines 60-66).

Chung disclose that biotin deficiency causes irregularities of fat metabolism including fatty liver and elevated palmitoleic acid concentration in the liver and cholesterol in the serum (Page 45). It is disclosed that biotin-rich ingredients significantly lowered serum LDL and triglyceride and increased HDL (Page 45).

Examiner has duly considered Applicant's arguments but deems them unpersuasive for the reasons set forth in the prior Office Actions and the further reasons below.

The Applicant argues that there are compositions, such as pioglitazone, metformin and rosiglitzone, which are useful in reducing hyperglycemia and stabilizing serum glucose which have no effect or even exacerbate cholesterol and/or triglyceride. However, said composition are not biotin or chromium which have been shown to increase HDL.

The Applicant argues that a skilled artisan would not be able to ascertain from Chung et al. that biotin alone raised serum HDL levels. The Applicant cites to Exhibits A, B, C, however, said references are not sufficient to overcome the rejection. "The reason for requiring evidence in declaration or affidavit form is to obtain the assurances that any statements or representations made are correct, as provided by 35 U.S.C. 25 and 18 U.S.C. 1001." Permitting a publication to substitute for expert testimony would circumvent the guarantees built into the statute. *Ex parte Gray*, 10 USPQ2d 1922, 1928 (Bd. Pat. App. & Inter. 1989). The Chung et al. reference indicates that the biotin rich product increased HDL. There is nothing in the Exhibits provided which refutes the conclusion that the biotin-rich ingredient increased HDL. Further, the claims do not exclude the presence of the other ingredients.

The Applicant argues that evidence of synergism has been provided. However, both McCarty '066 and McCarty '401 disclose the combination of biotin and chromium complex results in synergistic effects (McCarty '066, Column 2, lines 56-65; McCarty '401, Column 2, lines 49-57). Further, it is expected from the prior art that the combination of chromium complex and biotin-rich ingredients would result in increased HDL cholesterol levels. As such, the expectation is not based solely on treatment of an underlying disease. Further, one of ordinary skill in the art would expect that anyone would benefit from increased HDL levels.

Therefore, the claimed invention, as a whole, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made, because every element of the invention has been collectively taught by the combined teachings of the references.

Double Patenting

Claims 7, 38-54 are provisionally rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 1, 3-5, 7-20 of copending Application No. 11/136,794. Claims 7, 38-54 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-20 of copending Application No. 11/136,794. Although the conflicting claims are not identical, they are not patentably distinct from each other because Claim 7 of the '794 application discloses a method of treating dyslipidemia wherein the dylipidemia is caused by low levels of HDL cholesterol in the blood. As such, one of ordinary skill in the art would expect that the synergistically effective dose of chromium complex and biotin would be effective in treating said dyslipidemia by raising the levels of HDL cholesterol in the blood. Further, although the '794 application is the later filed application, claims of 1, 3-5, 7-20 of said application are also obvious in view of claims 7, 28-54 of the present application in

that claim 7 of the present application is also directed to treatment of dyslipidemia by administering a synergistically effective dose of chromium complex and biotin. As such, one of ordinary skill in the art would expect that the method of the present application would be effective in treating dyslipidemias where low levels of HDL in the blood is the cause of the dyslipidemia. As such, there is two-obviousness and the provisional double patenting rejection based on a later filed application is proper.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

A facsimile center has been established in Technology Center 1600. The hours of operation are Monday through Friday, 8:45 AM to 4:45 PM. The telecopier number for accessing the facsimile machine is 571-273-8300.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frank Choi whose telephone number is (571)272-0610. Examiner maintains a compressed schedule and may be reached Monday, Tuesday, Thursday, Friday, 6:00 am – 4:30 pm (EST).

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Johann R. Richter, can be reached at (571)272-0646. Additionally, Technology Center 1600's Receptionist and Customer Service can be reached at (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frank Choi
Patent Examiner
Technology Center 1600
May 2, 2008

/Johann R. Richter/
Supervisory Patent Examiner, Art Unit 1616